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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,694	05/22/2000	Anne Sorensen	Novo-029	3706

23650 7590 06/16/2004

NOVO NORDISK PHARMACEUTICALS, INC  
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EXAMINER

HON, SOW FUN

ART UNIT PAPER NUMBER

1772

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/577,694

Applicant(s)

SORENSEN ET AL.

Examiner

Sow-Fun Hon

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 43-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment***

***Withdrawn Rejections***

1. The 35 U.S.C. 112, 2<sup>nd</sup> paragraph rejections of claims 59-60 are withdrawn due to Applicant's amendment dated 03/15/04.
2. The 35 U.S.C. 102(b) rejection of claims 43-56, 58 are withdrawn due to Applicant's amendment dated 03/15/04.
3. The 35 U.S.C. 103(a) rejection of claims 57, 60 are withdrawn due to Applicant's amendment dated 03/15/04.

***New Rejections***

***Claim Rejections - 35 USC § 103***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 43-56, 58-59, 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai et al. (previously cited US 4,444,330).

Regarding claims 43, 47, 54, 61-62, Kasai et al. teaches a stopper which comprises an injection-mouldable blend of 30 to 90 weight % butyl based rubber and up to 30 weight % thermoplastic polymer (polyolefin) (column 1, lines 45-55) which overlaps the combination of the claimed range of 70-90 % by weight of butyl rubber and 30-10 % by weight of thermoplastic polymer (claims 43, 54, 62); and the narrower one of 75-87 % butyl based rubber and 13-25 % by weight of thermoplastic polymer (claim 47).

The thermoplastic polymer (polyolefin) is polypropylene or polyethylene, added to improve mouldability (column 1, lines 60-65). Although Kasai et al. fails to teach that the polyethylene and polypropylene are defined as only their respective homopolymers, the use of polyethylene and polypropylene homopolymers is notoriously well known in the art. The fact that polyethylene and polypropylene homopolymers are non-elastomeric is also notoriously well-known in the art (claim 62).

Kasai et al. teaches that the butyl rubber alone is subject to permanent set and cannot provide a stopper for hermetically sealing a medical container (column 2, lines 30-40) thus teaching that a stopper made from a combination of the butyl rubber and another component provides for a hermetically sealed container resulting in a reduced leakage of substances compared to a stopper made from butyl rubber alone.

Regarding the qualifier “consisting essentially of”, while Applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” Applicant has the burden of showing that the introduction of the additional component of a thermoplastic elastomer would materially change the characteristics of applicant’s invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). See MPEP 2111.03.

Regarding claim 44-46, 61, Kasai et al. teaches that the butyl rubber is blended with up to 30 % polypropylene or polyethylene (column 1, lines 45-55), the blend is homogenized with heating (kneaded in mixer at 150 °C to 250 °C), and the stopper is injection moulded (column 3, lines 55-65). Injection moulding requires the blend to be fluid, thus injection moulding at 250 °C means that the thermoplastic polypropylene or polyethylene is in the melt. Hence the

Art Unit: 1772

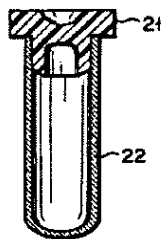
composition and process steps of stopper manufacture are similar in Applicant's specification (page 2, lines 25-30). Therefore a hardness of 40-80 Shore A in conformance with ASTM D2240, 5 sec., 1991 (claims 44, 58), of 45-75 Shore A in conformance with ASTM D2240, 5 sec., 1991 (claim 45), or of 65-75 Shore A in conformance with ASTM D2240, 5 sec., 1991 (claim 46) is the result of routine experimentation.

Regarding claims 48-49, the butyl based rubber is a halogenated one (column 1, lines 50-55) such as a bromobutyl rubber (column 2, line 65).

Regarding claim 50, the butyl based rubber is at least partially crosslinked (column 1, lines 50-55).

Regarding claim 51, Fig. 5 below show that the stopper 21 has a substantially circular cross-section.

Regarding claims 52-53, 56-57, Fig. 5 below shows that stopper 21 is in container body 22, and any way of pushing the stopper in, whether the applied force to the stopper is through a rod (claims 53, 57) or palm of a hand results in a stoppered container. It can be seen that the stopper can only glide longitudinally into the container body (claims 52, 56).

**F I G. 5**

Regarding claims 54-55, Kasai et al. teaches a medical container with non-flexible (hard) walls (column 1, lines 10-15). Fig. 5 above shows that the container 22 comprises a distal and a

Art Unit: 1772

proximal end, and at least one wall defining an interior space for storing liquid blood (column 5, lines 40-50). The term “medical container” means that the contents can be liquid medicament such as liquid infusion solution (column 1, lines 10-15).

Regarding claim 59, Kasai et al. provides an example of the process comprising mixing the butyl rubber and the thermoplastic polymer to form a stopper material, via heating (kneaded with a mixer) at 150 to 250 °C to pelletize them and then injection moulded at preferably 200 to 220 °C to form the stopper (column 3, lines 55-60). Since injection moulding is normally carried out at temperatures above the melting point of the injection moulding material, and the pelletizing stage above can use the same temperature range at which the injection molding is conducted (200 to 220 °C is within the pelletizing temperature range of 150 to 250 °C), the pelletizing stage conducts the three steps of heating the butyl based rubber, melting the thermoplastic polymer and homogenizing the material.

6. Claims 57, 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai et al. as applied to claims 43-56, 58-59, 61-62above, and further in view of Rheude (previously presented US 2,507,680).

Kasai et al. has been discussed above, and teaches a medical container for storing a liquid medicament, comprising a distal and a proximal end portion and at least one wall defining an interior space for storing liquid medicament, wherein one of the end portions comprises a stopper that is comprised of an injection-mouldable material made of a combination of butyl based rubber and a thermoplastic polymer, characterized in that the butyl based rubber is present in an amount of 70-90 % by weight and the thermoplastic polymer is present in an amount of 30-10 % by weight wherein the thermoplastic polymer is selected from the group of polyolefins

Art Unit: 1772

consisting of polypropylene and polyethylene, wherein their use in the form of homopolymers is well known in the art, and wherein the combination of the butyl based rubber and the thermoplastic polymer results in a reduced leakage of substances compared to the leakage of substances from a stopper made from butyl rubber alone.

Kasai et al. fails to teach a rod, or a rod moulded onto the stopper by the means of two-component injection moulding.

Rheude teaches a stopper for a container (bottle) which has a pusher rod 6 (column 2, lines 1-5). It can be seen in Fig 3 that the pusher rod results in the stopper being completely inserted into the neck of the container.

Anyone who has tried to shove a rubber stopper into a bottle neck knows how difficult it is to push it in completely. Rheude has shown that it would have been obvious to one of ordinary skill in the art to have attached a pusher rod to the stopper of Kasai et al. in order to facilitate insertion of the stopper into the neck of the container.

It would be an obvious variation to one of ordinary skill in the art to have moulded the rod of Rheude onto the stopper during the injection moulding step in the process of Kasai et al., which step would then have been termed two component injection moulding.

### ***Response to Arguments***

7. Applicant's arguments with respect to claims 43-60 have been considered but are moot in view of the new ground(s) of rejection.

In order to advance prosecution, however, Applicant is respectfully apprised that a stopper molded from an injection-moldable material consisting essentially of butyl rubber and

Art Unit: 1772

hompolymers of polypropylene or polyethylene excludes the additional component of thermoplastic elastomer taught by the prior art if Applicant has demonstrated that the introduction of the additional component of thermoplastic elastomer would materially change the characteristics of Applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). See MPEP 2111.03.

8. Furthermore, there is now agreement at the Office that by drafting claim language to recite that the stopper is made from material comprising, or consisting essentially of, or even consisting of, does not clearly exclude other components unless a negative limitation is inserted in the form of "in the absence of the additional components".

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,



Art Unit: 1772

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SH

Sow-Fun Hon

06/04/04

  
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1772

6/14/04